IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	) Novel Formulations Comprising Lipid-Regulating Agents
Lipari et al.	)
	) Group Art Unit: 1615
Serial No. 09/216,242	)
	) Examiner: Gollamudi S. Kishore
Filed: December 18, 1998	)

35/Suppl Appeal Brief (3)

BRIEF ON APPEAL

Bef 9-5-03

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the November 18, 2002 Final Office Action issued in the present application, Applicants filed a Notice of Appeal on February 18, 2003. This is the Appellants' Brief on Appeal filed pursuant to this Appeal.

---

37 CFR 1.8
CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service, as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on April 17, 2003.

Corinne Byk

Corinne Byk

TABLE OF CONTENTS

COMPLETE BRIEF ON APPEAL

BRIEF ON APPEAL

I. REAL PARTY IN INTEREST

The real party in interest is Abbott Laboratories, the Assignee of all rights and interests in the present application.

II. RELATED APPEALS AND INTERFERENCES

There are no known related pending appeals or interferences pending with regard to this application. However, Notices of Appeal have been filed in application Serial Numbers 09/215,831 and 09/216,247, which are directed to related subject matter and have been rejected over the same primary reference.

III. STATUS OF CLAIMS

The present application was filed with claims 1 to 20. Claims 2, 6-11, 13, 17 and 18 to 20 have been canceled. Claims 1, 3-5, 12 and 14-16 are at issue in this appeal.[1] There are two outstanding grounds of rejection as follows:

A. Claims 1, 3-5, 12 and 14-16 have been rejected under 35 U.S.C. §102(b) as being anticipated by Lacy et al. (U.S. Patent No. 5,645,856) ("Lacy"); and

---

[1] While claim 17 has been rejected by the Examiner, it was canceled in the Amendment mailed on September 19, 2001 and filed on September 24, 2001. Claim 17 will not be treated as part of this appeal.

B. Claims 1, 3-5, 12 and 14-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lacy, further in view of Babayan et al. (U.S. Patent No. 4,952,606) ("Babayan"), Bistrian et al. (U.S. Patent No. 4,871,768) ("Bistrian") and Hyltander et al. (NCP, Vol. 10, No. 3, pp. 91-97, June 1995) ("Hyltander").

IV. STATUS OF AMENDMENTS

As noted above, claims 2, 6-11, 13, 17 and 18-20 have been canceled. Claim 1 has been amended three times and claims 3, 14, 15 and 16 have been amended once. Claims 1, 3-5, 12 and 14-16, as presently amended, are set forth in the Appendix.

V. SUMMARY OF THE INVENTION

The present invention is directed to a composition consisting of a fibrate dissolved in at least one structured lipid. Structured lipids contain saturated medium (C_8 to C_{10}) and long-chain (C_{16} to C_{18}) fatty acids esterified to the corresponding glycerol molecule.

The compositions of the present invention advantageously provide improved bioavailability respecting commercially available formulations.

VI. ISSUES PRESENTED:

A. Are claims 1, 3-5, 12 and 14-16 patentably novel under 35 U.S.C. §102(b) over Lacy?

B. Are claims 1, 3-5, 12 and 14-16 patentably non-obvious under 35 U.S.C. §103(a) over Lacy further in view of Babayan, Bistrian and Hyltander?

VII. GROUPING OF CLAIMS

The claims are grouped in two (2) groups as follows:

A. Claims 1, 3, 12, 14, 15 and 16; and

B. Claims 4 and 5.

VIII. ARGUMENT

A. Rejection of claims 1, 3-5, 12 and 14-16 under 35 U.S.C. §102(b).

Claims 1, 3-5, 12 and 14-16 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lacy.

Each claim is directed to a composition consisting of a fibrate dissolved in at least one structured lipid. Lacy fails to anticipate the claims because Lacy fails to disclose solvents that are structured lipids and because Lacy necessitates the inclusion of surfactants in addition to solvents.

Anticipation can only be established by a single prior art reference that discloses each and every element of the claimed invention. RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440, 1444, 221 U.S.P.Q. 385, 388 (Fed. Cir. 1984).

As set forth in claim 1, the transition phrase "consisting of" applies to each claim closing each claim to the inclusion of materials other than those recited except for impurities

ordinarily associated therewith. Ex parte Davis and Tuukkanen, 80 U.S.P.Q. 448, 450 (Bd. App. 1949), Mannessman Demag Corp. v. Engineered Metal Products Co., Inc., 793 F.2d 1279, 230 U.S.P.Q. 45 (Fed. Cir. 1986), Vehicular Technologies Corp. v. Titan Wheel International, Inc., 54 U.S.P.Q.2d 1841, 1845 (Fed. Cir. 2000).

As noted above, the claims are directed to compositions consisting of a fibrate dissolved in at least one structured lipid and to their use to treat hyperlipidemia. At page 3, lines 34-39, several suitable structured lipids are identified for use in the present invention. (See also claims 4 and 5.)

Hyltander teaches that structured lipids contain saturated medium-(C_8 to C_{10}) and long-chain (C_{16} to C_{18}) fatty acids esterified to the corresponding glycerol molecule (Hyltander; Editorial pg. 89 and pg. 91). Structured lipids are distinguishable from physical mixtures of medium- and long-chain triglycerides.

Lacy discloses a carrier for hydrophobic drugs comprising a digestible oil and a pharmaceutically acceptable surfactant component for dispersing the oil *in vivo* (Abstract). The surfactant comprises a hydrophilic surfactant component, preferably a mixture of a lipophilic surfactant component and a hydrophilic surfactant component (column 3, lines 38-66). Lacy discloses a three component system (a drug, a digestible oil and surfactant system) (column 4, lines 8-14).

Lacy fails to disclose a two component composition, i.e., a composition consisting of a drug (i.e., a fibrate) dissolved in at least one structured lipid. Lacy requires the inclusion of a third component, i.e., the surfactant component. Thus, Lacy fails to anticipate

claim 1 and the claims dependent thereon. Lacy not only fails to anticipate the claims; it teaches away from the claimed invention. A reference must be considered for all that it teaches, including disclosures that diverge and teach away from the invention. In re Dow Chem. Co., 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988). A reference teaches away when a person of ordinary skill, upon reading it, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the inventor. Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 45 USPQ2d 1977 (Fed. Cir. 1998).

Lacy fails to disclose the use of structured lipids broadly or the preferred structured lipids set forth in claims 4 and 5.

In discussing Lacy, the Office Action dated November 18, 2002, at Paragraph 2, stated that the reference

> "discloses capsules containing solutions of fenofibrate. The emulsions contain a triglyceride, propylene glycol fatty acid esters, polyglycerol esters of fatty acids and a co-solvent".

Even if one was to accept this characterization of the teachings of Lacy, Lacy clearly fails to disclose "a composition consisting of a fibrate dissolved in at least one structured lipid" as required by claim 1. Thus, claim 1 and those claims dependent thereon are patentably novel over Lacy.

The Office Action dated November 18, 2002, at Paragraph 2, also stated that the Lacy composition

> "further contains Capric/caprylic triglycerides such as Miglyol™ and Captex™ (note columns 4 and 5 and Examples 6 and 7)".

The Miglyol and Captex referred to in columns 4 and 5 of Lacy are Miglyol 829, a caprylic/capric diglyceryl succinate (column 4, line 66), which is a glyceryl ester of caprylic/capric/succinic acids; and Captex 200 and Miglyol 840, a propylene glycol dicaprylate/dicaprate (column 5, lines 14 and 15), which is a propylene glycol ester of caprylic/capric acids. These materials are not structured lipids, as they do not contain both saturated medium-(C8 to C10) and long-chain (C16 to C18) fatty acids esterified to the same glycerol molecule (NCP, Vol. 10, No. 3, pp. 89-90, June 1995 and Hyltander).

In Examples 6 and 7 of Lacy, fractionated coconut oil is disclosed. Fractionated coconut oil is a caprylic/capric triglyceride. Several such products are referred to in Lacy: Miglyol 810, Miglyol 812, Captex 300, Captex 355, and Captex 8000 (column 9, lines 20-28). These materials are caprylic and/or capric triglycerides (medium-chain triglycerides) and are not structured lipids as required by the claims. Structured lipids contain both saturated medium-(C8 to C10) and long-chain (C16 to C18) fatty acids esterified to the same glycerol molecule (NCP, Vol. 10, No. 3, pp. 89-90, June 1995 and Hyltander). In addition, structured lipids have a novel chemical structure and should be distinguished from physical mixtures of medium-chain and long-chain triglycerides (NCP, Vol. 10, No. 3, pp. 89-90, June 1995).

Thus, for the reasons stated above, claim 1 and all of those claims dependent thereon are not anticipated by Lacy.

It should also be noted that, in making the §103(a) rejection, the Office Action dated November 18, 2002, at Paragraph 4, stated that Lacy

> "discloses capsules containing solutions of fenofibrate. The emulsions contain a triglyceride, propylene glycol fatty acid esters, polyglycerol esters of fatty acids and a co-solvent".

Thus, it has been acknowledged that the compositions of Lacy contain essential components other than fenofibrate and triglycerides which are alleged to be the claimed structured lipids. Therefore, Lacy fails to anticipate the claims that are directed to a composition consisting of a fibrate dissolved in at least one structured lipid.

Claims 4 and 5 necessitate the presence of specific structured lipids (i.e., caprylic/capric/lauric triglycerides and caprylic/capric/linoleic triglycerides) that are not disclosed in Lacy. Thus, Lacy does not anticipate claims 4 and 5 because there is no disclosure of the specific structured lipids required by each claim.

For the above noted reasons, claims 1, 3-5, 12 and 14-16 are patentably novel over Lacy. Reversal of this rejection is respectfully requested.

B. Rejection of Claims 1, 3-5, 12 and 14-16 under 35 U.S.C. §103(a).

The Office Action rejected claims 1, 3-5, 12 and 14-16 under 35 U.S.C. §103(a) as being unpatentable over Lacy, further in view of Babayan, Bistrian and Hyltander, individually or in combination. The Office Action dated November 18, 2002, at Paragraph 4, stated that

> "it is deemed obvious to one of ordinary skill in the art to use the structured triglycerides instead of the triglycerides taught by Lacy et al., especially when the drug used is for regulating cholesterol or lipid metabolism, since structured triglycerides have advantages relating to cholesterol and atherosclerosis and other clinical advantages as taught by Babayan et al., Bistrian et al. and Hyltander et al., respectively".

Babayan, Bistrian and Hyltander each disclose the use of structured lipids in dietary supplements for nutritional purposes. For example, Hyltander discloses the use of structured triglycerides as an I.V. nutrient source (ABSTRACT); Babayan discloses the use of certain structured lipids "for a variety of nutritional applications and methods of treating hypercatabolic mammals with nutritional therapy" (column 1, lines 66-68) using the structured lipid as the primary fat source in said therapy (claim 13); and Bistrian discloses the use of structured lipids as a dietary supplement (ABSTRACT).

None of these references teach or even remotely suggest the use of structured lipids for use as a solvent for a therapeutic agent. None of these references teach or suggest the use of structured lipids in combination with any drug or class of drugs (e.g., a fibrate) in therapeutic compositions. None of these references teach or suggest the use of structured lipids in capsules. None of these references suggests that nutritional agents are interchangeable with fibrate. Thus, there is no motivation to substitute the structured lipids disclosed as nutritional supplements in the secondary references for the triglyceride solvents of Lacy.

Even if there were some proper motivation to substitute the structured lipids of the secondary references for the digestible oils of Lacy, one would not obtain "a composition

consisting of a fibrate dissolved in at least one structured lipid" as required by the claims. One would, as noted in the Office Action, obtain a composition that also contains as essential components propylene glycol fatty acid esters, polyglycerol esters of fatty acids and a co-solvent. The claims explicitly exclude the presence of these other components. Additionally, there is no disclosure in any of the references of the specific structured lipids required by claims 4 and 5.

For the above stated reasons, no combination of Lacy, Babayan, Bistrian and Hyltander renders claims 1, 3-5, 12 and 14-16 unpatentable under 35 U.S.C. §103(a) and this rejection should be reversed. Claims 1, 3-5, 12 and 14-16 are patentably non-obvious over Lacy in view of Babayan, Bistrian and Hyltander.

IX. CONCLUSION

The rejection of claims 1, 3-5, 12 and 14-16 should be reversed and this application should be remanded for the issuance of a Notice of Allowance.

Respectfully submitted,

WOOD, PHILLIPS, KATZ,
CLARK & MORTIMER

Date: April 17, 2003

By _____
Martin L. Katz, Reg. No. 25,011

Citicorp Center
500 West Madison Street
Suite 3800
Chicago, IL 60661-2511
(312) 876-1800

APPENDIX - CLAIMS AT ISSUE

Claim numbers 1, 3-5, 12, 14-16 are at issue and read as follows:

1. A composition consisting of a fibrate dissolved in at least one structured lipid.

3. A composition of claim 1 wherein the fibrate is fenofibrate.

4. A composition of claim 1 wherein at least one or more of the structured lipids is selected from the group consisting of caprylic/capric/lauric triglycerides and caprylic/capric/linoleic triglycerides.

5. A composition of claim 4 wherein the structured lipid is a caprylic/capric/lauric triglyceride.

12. A capsule comprising a composition of claim 1.

14. A capsule of claim 12 wherein the fibrate is fenofibrate.

15. A method of treating hyperlipidemia comprising the step of administering a therapeutically-effective amount of a composition of claim 1 to a patient.

16. A method of treating hyperlipidemia comprising the step of administering a therapeutically-effective amount of a composition of claim 3 to a patient.